IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY, Plaintiff, v. TEVA PARENTERAL MEDICINES, INC., APP PHARMACEUTICALS, LLC, PLIVA HRVATSKA D.O.O., TEVA PHARMACEUTICALS USA, INC., and BARR LABORATORIES, INC., Defendants.	)	Civil Action No. 1:10-cv-01376-TWP-DKL

DEFENDANTS' CORRECTED POST-TRIAL BRIEF REGARDING PLAINTIFF'S ALLEGATION OF INFRINGEMENT OF U.S. PATENT NO. 7,772,209

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Abbreviation	Description
"Teva"	Teva Parenteral Medicines, Inc. and Teva Pharmaceuticals USA, Inc.
"APP"	APP Pharmaceuticals, LLC
"Defendants"	Teva and APP
"Lilly" / Eli Lilly"	Eli Lilly and Company
"asserted claims"	Claims 9, 10, 12, 14, 15, 18, 19, and 21 of the '209 patent
"Lilly Br."	D.I. 410, Plaintiff Eli Lilly and Company's Opening Post-Trial Brief
"TX"	Trial Exhibit
"Tr."	Official Reporter's Transcript of Bench Trial held on May 28, 2015
"ANDA"	Abbreviated New Drug Application
"POSA"	Person of ordinary skill in the art
"the '209 patent" / "patent-in-suit"	U.S. Patent No. 7,772,209 (TX 1; attached hereto)
"Lilly Amicus Brief"	Brief of Amicus Curiae Eli Lilly and Company, Supporting Respondents, *Limelight Networks, Inc. v. Akamai Techs., Inc.*, No. 12-786, 2014 WL 1319146 (U.S. Apr. 2, 2014) (attached as Ex. A)
"TX 3018" or "prescribing information"	ALIMTA® prescribing information, revised 09/2013 (TX 3018; attached hereto)
"TX 3017" or "patient information"	ALIMTA® patient information, revised 09/2013 (TX 3017; attached hereto)
"TX 1379" or "11/2012 prescribing information"	ALIMTA® prescribing information, revised 11/2012 (TX 1379; attached hereto)
"TX 2037" or "05/2012 prescribing information"	ALIMTA® prescribing information, revised 05/2012 (TX 2037; attached hereto)
"PDR"	PDR Medical Dictionary, 1st Edition, Medical Economics, pg. 1422 (1995) (attached as Ex. B)
"Stedman's"	Stedman's Medical Dictionary, 26th Edition, William & Wilkins, pg. 1422 (1995) (attached as Ex. C)

"Taber's"	Taber's Cyclopedic Medical Dictionary, 19th Edition, pg. 1743, F.A. Davis Company (2001) (attached as Ex. D)
"U.S. Patent No. 7,470,506" or "the '506 patent"	U.S. Patent No. 7,470,506 (attached as Ex. G)
"FDA Guidance"	U.S. Dept. of Health and Human Services, *Guidance for Industry, Dosage and Administration Section of Labeling for Human Prescription Drug and Biological Products—Content and Format*, March 2010 (attached as Ex. F)
"Teva's October 2012 Interrogatory Responses"	Defendants' October 5, 2012 Supplemental Responses To Plaintiff Eli Lilly and Company's Interrogatories Nos. 1-3 and 15 (attached as Ex. E)

I. Introduction

Lilly has not proven that the Defendants will indirectly infringe the asserted claims of the '209 patent because no single entity will practice each step of the claimed method. The asserted claims of the patent-in-suit require that three compounds be administered—folic acid, vitamin B12, and pemetrexed—in a certain order and at certain doses. As drafted, the claims do not specify ***who*** will administer each compound. The evidence at trial established that, as set out in the product labeling, the doctor, or other medical care provider, will administer vitamin B12 (by injection) and pemetrexed (by infusion). But the doctor will ***not*** administer folic acid; rather, the doctor will merely "instruct patients to initiate folic acid 400 mcg to 1000 mcg orally once daily." TX 3018 at 2. It will then be up to the patient to obtain folic acid, at the dose and in the form the patient chooses. "You can get folic acid vitamins over-the-counter. Folic acid is also found in many multivitamin pills. Ask your doctor or pharmacist for help if you are not sure how to choose a folic acid product." TX 3017 at 2. The patient may then administer folic acid daily by taking the vitamin or multi-vitamin at the dose and time she chooses.

As recently reiterated by the Federal Circuit, the Defendants cannot be found to infringe the asserted claims under these facts. Lilly has not asserted the Defendants directly infringe the '209 patent. Rather, Lilly asserts that Defendants induce or contribute to infringement. For a finding of such indirect infringement, Lilly must first prove that a single actor performs each step of the claimed method. *See Akamai Techs., Inc. v. Limelight Networks, Inc*., 786 F.3d 899, 904 (Fed. Cir. 2015). But the evidence at trial demonstrated that no single person carries out all the claimed steps of the method, and hence there is no direct infringement. Lacking proof of direct infringement, Lilly cannot prove Defendants indirectly infringe. *Limelight Networks, Inc. v. Akamai Techs., Inc.*, 134 S. Ct. 2111, 2117 (2014).

Lilly offers three arguments to establish that doctors directly infringe the asserted claims,

and hence provide a basis to find Defendants liable for indirect infringement. Each argument fails. First, Lilly argues that the word "administer" should be construed to include "prescribing and instructing" so that the conduct of the doctor concerning folic acid is covered by the claims. But this is not how the term is used in the intrinsic record or the common meaning, which instead means putting on or into the patient's body. Moreover, even if Lilly is correct, the term "administer" also requires that the drug get into the patient's body; as there is no dispute that the patient herself takes folic acid, there is no infringement even under Lilly's construction. Second, Lilly argues that a narrow exception to the single actor rule, which allows the actions of more than one individual to be combined in limited circumstances, applies here. Lilly is wrong. The Federal Circuit has explained that a single mastermind is responsible for the conduct of others only where they exercise "control or direction" such that the others are legally obligated to follow the leader, and the mastermind is legally responsible for their conduct. *Akamai*, 786 F.3d at 915. The doctor-patient relationship does not meet this high standard. Finally, Lilly argues that the conduct of the doctor in instructing patients to take folic acid is "equivalent" to actually administering the vitamin. No court has found that the conduct of two individuals (the doctor instructing and the patient administering) is equivalent to the conduct of a single actor. Lilly's equivalents theory should be rejected as legally and factually flawed.

II. The Facts Established At Trial Demonstrate That No Single Actor Carries Out Each Step Of The Claimed Methods

The '209 patent claims recite "administering" folic acid and vitamin B12 prior to "administering" pemetrexed. The parties agree that claim 12 is exemplary:

> An improved method for *administering* pemetrexed disodium to a patient in need of chemotherapeutic treatment, wherein the improvement comprises:
>
> a) *administration* of between about 350 µg and about 1000 µg of folic acid prior to the first *administration* of pemetrexed disodium;

> b) *administration* of about 500 µg to about 1500 µg of vitamin B12, prior to the first *administration* of pemetrexed disodium; and
>
> c) *administration* of pemetrexed disodium.

TX 1 at 11:25-12:5 (emphasis added).

The Defendants in this case seek FDA approval to market generic forms of pemetrexed. Defendants further seek to sell their pemetrexed products with prescribing information (TX 3018) and patient information (TX 3017) that provide certain instructions to both doctors and patients. The prescribing information provides:

> The recommended dose of [pemetrexed] is 500 mg/m^2 *administered* as an intravenous infusion . . . .
>
> *Instruct* patients to initiate folic acid 400 mcg to 1000 mcg orally once daily beginning 7 days before the first dose of [pemetrexed] . . .
>
> *Administer* vitamin B12 1 mg intramuscularly 1 week prior to the first dose of [pemetrexed]. . . .

TX 3018 at 2 (emphasis added). In addition to the prescribing information, Defendants seek to provide patient information (TX 3017), which is provided by the doctor to the patient. Tr. 147, 213-14. The patient information states:

> You must start taking 400-1000 micrograms of folic acid every day for at least 5 days out of the 7 days before your first dose of [pemetrexed]. You must keep taking folic acid every day during the time you are getting treatment with [pemetrexed] and for 21 days after your last treatment. You can get folic acid vitamins over-the-counter. Folic acid is also found in many multivitamin pills. Ask your doctor or pharmacist for help if you are not sure how to choose a folic acid product.

TX 3017 at 2. Defendants provide no further instructions to doctors or patients regarding the administration of folic acid. To the extent doctors provide more detail to patients concerning folic acid, or take action to confirm or ensure patients have complied with instructions to take folic acid, those actions are not encouraged or directed by Defendants but rather are done based

on the independent medical judgment of the doctors. Tr. 148, 151, 163.

Dr. Schulz and Dr. Chabner agreed that, following these labels, the doctor or other medical professional will administer the vitamin B12 (by injection) and pemetrexed (by infusion). Tr. 138, 139, 141, 189. But the evidence also demonstrated that it is the patient who takes folic acid. Tr. 141, 146-47, 189. And that folic acid is obtained by the patient without a prescription, in whatever form the patient chooses. Tr. 150, 214-15. While doctors may expect patients to follow these instructions, Defendants' labels do not induce physicians to take any actions other than instructing patients to administer folic acid (*e.g.*, the label does not require physicians to confirm folate levels before administering pemetrexed). Tr. 163, 216-18, 222. In the end, the patient decides whether to take folic acid, in what form, on what schedule and at what dose. Tr. 163-64, 214-15.

III. The Term "Administering" In The '209 Patent Claims Requires Pemetrexed, Vitamin B12, And Folic Acid To Be "Put On Or Into The Patient's Body"

The claims and specification—the most important sources of evidence for claim construction—consistently use the terms "administering," "administered," "administration," and "administer" (collectively, "administering") to refer to putting various agents into a patient's body. In particular, the claims and specification use "administering" to refer to how the agents are put into the body, when they are put into the body, and at what doses. The term "administering" should be given its plain and ordinary meaning in the context of the '209 patent, putting on or into the patient's body.

Lilly's proposed construction has been a moving target. Lilly seeks to have the Court construe the patent in an attempt to avoid the divided infringement issue created by the common meaning of the claims as Lilly drafted them. Lilly has now settled on a construction in its post-trial brief: instructing or prescribing an agent to a patient, and causing the patient to receive it.

See Lilly Br. at 6, 9. But Lilly's support is almost entirely ***extrinsic*** evidence, contrary to the Federal Circuit's instructions. The Court should reject Lilly's argument.

A. Defendants' Construction Is Supported By Intrinsic And Extrinsic Evidence

1. Defendants' Construction Stays True To The Claims And Specification Of The '209 Patent

Defendants' construction for "administering," putting on or into the patient's body "stays true to the claim language and most naturally aligns with" the specification of the '209 patent. *Renishaw PLC v. Marposs Societa'per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998). That is the "correct" way for determining what a claim term means. *Id.* As the Federal Circuit has stated, "[a]scertaining the meaning of the claims requires that they be viewed in the context of 'those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean.'" *MBO Labs., Inc. v. Becton, Dickinson & Co.*, 474 F. 3d 1323, 1329 (Fed. Cir. 2007) (quoting *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) (en banc)). "The most relevant source is the patent's specification**,** which is '*the single best guide to the meaning of a disputed term*.'" *Id.* (emphasis added) (quoting *Phillips*, 415 F.3d at 1315). On the other hand, "[e]xtrinsic evidence—testimony, dictionaries, learned treatises, or other material not part of the public record associated with the patent—may be helpful but is '*less significant than the intrinsic record* in determining the legally operative meaning of claim language.'" *Id.* (emphasis added) (quoting *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 862 (Fed. Cir. 2004)).

The claims and specification of the '209 patent dictate that "administering" requires putting the claimed agents into the patient's body. For example, claims 1 and 12, the only two independent claims, refer to a "patient" in need of pemetrexed or chemotherapy, and require administering folic acid and vitamin B12 prior to administering pemetrexed. TX 1 at 10:56-65,

11:25-12:4; Tr. 194-95. The Court previously defined a "patient" as a human undergoing medical treatment. D.I. 115 at 21. A human can only be undergoing treatment if the chemotherapy, here pemetrexed, is actually put into her body. Tr. 194-95.

But the claims and the specification of the '209 patent go further, and consistently use the term "administering" to refer to the physical act of putting medication into a patient's body, *i.e.*, the dose, route, and/or schedule of administration for pemetrexed, folic acid, and vitamin B12. TX 1 at 4:9-14, 6:35-40, 8:42-43, 8:46-48; Tr. 194-206. For example, claim 14 states that vitamin B12 is "administered by intramuscular injection," *i.e.*, put into the body by intramuscular injection, and claim 16 states that folic acid is "administered orally," *i.e.*, put into the body orally. TX 1 at 12:7-9; Tr. 196. *See also AstraZeneca AB v. Hanmi USA, Inc.*, No. 11-760, 2012 U.S. Dist. LEXIS 175666, at *14-16 (D.N.J. Dec. 10, 2012) (looking to specification and adopting construction similar to Defendants where the term "administration" referred to the claimed "oral" route of administration). Various claims, such as claims 1, 12, and 19, use "administering" to refer to ***when*** the agent gets put into the body. TX 1 at 10:56-65, 11:25-12:4, 12:18-20; Tr. 197-99. And various claims, such as claims 14 and 16, use "administering" to refer the amount of drug that gets put into the body. TX 1 at 12:7-9, 12:12-13; Tr. 196.[1] These claims do not dictate how a patient is informed about the drugs they will receive—they do not cover only instructions that are given "orally." Nor are they directed to the timing of those instructions or prescriptions—it does not matter if the doctor mentions pemetrexed "prior to" folic acid. Lilly never even mentions these uses of the term "administration" in claim 12 or the dependent claims asserted.

Moreover, as Dr. Schulz explained, the specification of the '209 patent similarly uses

[1] Lilly argues that the language of claim 21 is inconsistent with Defendants' construction. Lilly Br. at 10-11. Lilly is incorrect. As Defendants pointed out at trial, Tr. 61-2, the dispute concerning claim 21 is really about how a POSA would understand "discontinued" in the claim. Lilly does not even address this issue.

"administering" to describe details concerning how agents are put into the body of the patient, when to put them in, and in what quantity. Tr. 202-06 (citing TX 1 at 4:9-14, 6:35-40, 8:42-44, 8:46-48). The specification also explains that folic acid must be put into the patient's body to tolerate pemetrexed therapy. *See* TX 1 at 6:28-34 (identifying that folic acid needs to be put into the body to load folate stores weeks before antifolate treatment); Tr. 199-200. Therefore, the term "administering" requires putting folic acid into the patient's body so that the '209 patent's goal of building folate stores prior to administration of pemetrexed to prevent toxicity is achieved.

Lilly does not dispute that the '209 patent claims and specification use the term "administering" to mean putting agents on or into a patient's body. But Lilly argues that so long as they can point to a single instance in the specification in which some form of the word is used more broadly, the Court cannot adopt Defendants' proposed construction. Lilly Br. at 12 n.4. Lilly is wrong. The cases cited by Lilly pre-date the Federal Circuit's *en banc* decision in *Phillips* concerning claim construction, and rely upon a now-rejected approach to claim construction. 415 F.3d at 1319. Moreover, in those cases, there was no argument by the proponent of the narrower construction that the construction was necessitated by the patent claims. Here, however, the use of the term "administer" in the claims themselves necessitates construing the term to require putting on or into the body. Finally, in Lilly's cited cases, the narrower construction was solely based on a preferred embodiment in the specification; here, Defendants do not seek to import any limitations from the specification.

Lilly also argues that Defendants' construction should not be adopted unless Defendants can show the intrinsic record "expressly redefined the term" or "clearly disavowed some portion of its full scope." Lilly Br. at 5. That is incorrect. Defendants are properly arguing for the

common meaning of "administering" in the context of the '209 patent. "Properly viewed, the 'ordinary meaning' of a claim term is its meaning to the ordinary artisan *after reading the entire patent*," not what it means in the abstract based on extrinsic evidence. *Phillips*, 415 F.3d at 1321 (emphasis added). Defendants are using the ***claims and specification*** to interpret the common meaning of "administering." *See Enzo Biochem Inc. v. Applera Corp*., 780 F.3d 1149, 1156 (Fed. Cir. 2015) ("using the specification to more fully understand what the patentee claimed," in contrast to using the specification to limit the meaning of a claim term). It is undisputed the term is used in the claims and specification to refer to putting agents into the patient's body, thus informing the "ordinary" meaning for "administering."

2. Defendants' Construction Is Consistent With Expert Testimony And Lilly's Amicus Brief Regarding Method Claims

Because analysis of the above intrinsic evidence shows that "administering" should be construed as putting an agent into the body, consideration of any extrinsic evidence is unnecessary. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996). To the extent the Court does review extrinsic evidence, however, it must be consistent with the claims and specification of the '209 patent. *SkinMedica, Inc. v. Histogen Inc.*, 727 F.3d 1187, 1210 (Fed. Cir. 2013).

Both testifying experts agreed at trial that "administering" refers to putting an agent into the patient's body. Dr. Schulz, Defendants' medical expert, has treated 5,000 to 10,000 cancer patients, and has also prescribed pemetrexed 500 to 1,000 times. Tr. 183-85. He explained that "administering" is ordinarily used in the medical field to refer to "putting an agent into or onto the body." Tr. 188. And during cross-examination, Dr. Chabner agreed that the administration of a drug is not completed until it has been put into the patient's body. Tr. 138, 141, 146-47,

153-54.[2]

Lilly conceded that the common meaning of administer was different from merely prescribing in its amicus brief to the Supreme Court in *Limelight Networks, Inc. v. Akamai Techs., Inc*., No. 12-786, 2014 WL 1319146, at *9 (U.S. Apr. 2, 2014) ("Lilly Amicus Brief"; Ex. A). In that brief, Lilly unsuccessfully argued that the Supreme Court should allow proof of indirect infringement even without a holding that any single party practiced each element of the claims. *Id*. at *9. Lilly argued that "[m]ethod of treatment claims routinely and sometimes necessarily present divided infringement issues," and if the law was reversed (as it has now been), it could not assert infringement of such claims. *Id.* at *9-13. Lilly explained:

> For example, arguments have been made that even a simple claim directed for example to a "method of treating disease X comprising administering drug Y to a patient in need thereof," requires multiple actors to infringe the claim . . . [A] physician will be required to diagnose the disease and *write a prescription for a patient* in need thereof, a pharmacist will fill the prescription, and *a patient or another healthcare provider will administer the drug*. The situation is even more complicated with *combination therapy claims where more than one drug is administered* to a patient or with method claims that require a doctor to determine whether a particular marker is present or absent in a biological tissue before writing a *prescription or administering a drug*. Thus, for method of treatment claims it is not uncommon that to practice all the steps, a doctor, nurse, laboratory technician, pharmacist, and patient may be needed.

Id. at *9-10 (emphasis added).[3] Lilly explicitly distinguished "administering" from "prescribing"; now, however, Lilly argues that the Court should construe the '209 patent based

[2] Furthermore, as discussed in Defendants' pre-trial brief (D.I. 368 at 13), prior art references authored or sponsored by Lilly and relating to pemetrexed, use the term "administering" to refer to the act of putting an agent, like pemetrexed or folic acid, into a patient's body, by referring to the dose, route, and/or schedule for that agent.

[3] In its post-trial brief, Lilly tries to distance itself from its admissions, arguing that it is not Lilly's argument, and that they did not relate to the field of oncology. Lilly Br. at 13 n.5. But Lilly's attempt to recant its previous arguments is futile. In the excerpt cited above, Lilly, in its own words, and not in the words of the patent challenger, explained why the example poses a joint infringement problem, and in doing so, distinguished between prescribing and administering. Moreover, Lilly's example was clearly addressed to patents in the field of oncology. In a footnote in the same paragraph as its example, Lilly cited one of its patents directed to treating pancreatic cancer. *Id*. at *10 n.5.

upon an alleged "common meaning" so that they are one and the same. The Court should reject Lilly's argument, which is directly contrary to what it told the Supreme Court.

B. Lilly's Construction Should Not Be Adopted

As noted above, Lilly's construction of administer, like Defendants', includes putting the agent into the body. But Lilly seeks to require that the term include other conduct. The Court, however, should not adopt Lilly's proposed construction, because it improperly reads additional action into the claim term "administering."[4] Lilly's construction is entirely dependent on extrinsic evidence and ignores intrinsic evidence. Lilly's motivation is clear. Rather than simply giving the common meaning to the disputed claim term, Lilly is using hindsight knowledge of the divided infringement case law to change the plain meaning of the term "administer" to encompass the doctor's actions. The Court should reject Lilly's construction.

1. Lilly's Claim Construction Improperly Relies On Extrinsic Evidence

Lilly's construction heavily depends on its strained interpretation of extrinsic evidence. The Federal Circuit has explained that "undue reliance on extrinsic evidence poses the risk that it will be used to change the meaning of claims in derogation of the 'indisputable public records consisting of the claims, the specification and the prosecution history,' thereby undermining the public notice function of patents." *Phillips*, 415 F.3d at 1319 (quoting *Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1578 (Fed. Cir. 1995)). That is exactly what Lilly's reliance on extrinsic evidence threatens to do here.

a. Dr. Chabner's Testimony Is Incomplete, Inconsistent With The Intrinsic Evidence, And Conclusory

Lilly primarily relies on its expert, Dr. Chabner, to define "administering." *E.g.*, Lilly Br. at 5-6. During his examination, Dr. Chabner testified that "administering" meant "choosing the

[4] Lilly's proposed construction has changed throughout this case. Defendants here address what appears to be the proposed construction now offered in Lilly's post-trial brief.

right regimen, writing the orders, and being sure that they're carried out by the parties that are responsible for each step" or "being responsible for organizing and giving a regimen." Tr. 83, 84, 159. This is not even Lilly's construction, as Lilly has disclaimed including "being sure that they're carried out" as part of its construction. Lilly Br. at 14. Regardless, this testimony cannot be relied upon to construe the term. First, Dr. Chabner's testimony was incomplete. Dr. Chabner did not even address the claims and portion of the specification that Lilly does not dispute supports Defendants' construction of "administering." Second, Dr. Chabner's testimony was also inconsistent with the intrinsic record. His constructions make no sense in the '209 patent claims, or in various excerpts from the specification, that use "administering" to refer to how or when an agent gets into the body. Finally, Dr. Chabner's testimony was conclusory. There was no documentary evidence—dictionary definition, articles, etc.—to support his constructions.[5] For at least these reasons, Dr. Chabner's testimony should be given no weight. *Phillips*, 415 F.3d at 1318; *SkinMedica*, 727 F.3d at 1210 (affording expert testimony "no weight" with regard to claim construction where it was "conclusory and incomplete[,] lack[ed] any substantive explanation tied to the intrinsic record[,] and . . . appear[ed] to conflict with the plain language of the written description").

b. Dr. Schulz Does Not Agree With Lilly's Construction

Lilly is wrong when it argues that Dr. Schulz agrees with Lilly's construction of "administering." Lilly Br. at 7, 8. While Dr. Schulz acknowledged that in some contexts (different than the '209 patent), administering can have a different meaning than he proposed, he never agreed that it would include prescribing ***and instructing and directing***. Even if the Court

[5] Medical dictionaries available as of the filing of the '209 patent define prescribing as different than administering. *See* Ex. B (PDR) at 1422 (defining "prescribe" as "to give directions, either orally or in writing, for the *preparation and administration of a remedy* to be used in the treatment of any disease") (emphasis added); Ex. C (Stedman's) at 1422 (same); Ex. D (Taber's) at 1743 (defining "prescribe" as "to indicate the medicine to be administered.").

were to hold that administering includes physically providing a pill for a patient to take or even prescribing, there is no support for the additional portions of Lilly's proposed construction. And in the context of the '209 patent, Dr. Schulz explained that administering means putting an agent into a patient's body, consistent with the claims and specification of the '209 patent. *See* Tr. 193-94. He explained the alternative ways to use the term, the physician overseeing the taking of, or prescribing a drug, are inconsistent with the '209 patent. Tr. 206-07.[6] These alternate uses do not change the meaning of "administering" in the '209 patent. *Id.*

Finally, Lilly refers to Dr. Schulz's expert report on an ***unrelated*** issue, and his use of the word "administering" to describe how ***Lilly***, a drug company, carried out clinical studies in which patients received folic acid, vitamin B12, and pemetrexed. Lilly Br. at 7. But no one is arguing that this reflects how a POSA would understand the term "administering." Indeed, Lilly agrees that drug companies do not administer drugs. Tr. 139, 141. Dr. Schulz's use of the term here was simply in a different context from that used in the '209 patent.

c. The Alimta® Prescribing Information Does Not Support Lilly's Construction

Lilly heavily relies on the extrinsic prescribing information for Alimta® to support its construction. Lilly Br. at 6-7. But the prescribing information is irrelevant to claim construction. It was drafted by Lilly, not a person of ordinary skill in the art, well after the application that led to the patent in suit was filed. Moreover, the information notably does ***not*** indicate that folic acid is "administered" by the doctor—to the contrary, for folic acid, the

[6] Lilly cites the cross-examination of Dr. Schulz to argue that he conceded that the term administer has a broader meaning than simply putting an agent into the patient's body. Lilly Br. at 8. While Dr. Schulz did agree that, in the context of an article, he and his co-authors used the word "administered" to describe a clinical trial in which the patient took the chemotherapy drug orally, Dr. Schulz had already explained that this article did not redefine the term, in all contexts, to be as broad as Lilly argues. Tr. 206; *see also* TX 1160 at 347 (The chemotherapy "had not yet been developed to allow for home administration. This situation necessitated that all patients come to the clinic weekly to pick up the chemotherapy."). As this extrinsic evidence is inconsistent with the use of the term administer in the context of the '209 patent, and completely different than how patients obtain folic acid, it does not support Lilly's proposed construction.

information merely says that a doctor should "instruct" the patient. TX 3018 at 2. That the most recent version of the prescribing information drafted by Lilly after Defendants had disclosed their non-infringement position indicates that dexamethasone (which is only available by prescription) should be "administered" does not support Lilly's broad construction.

First, a POSA would not have even considered the Alimta® prescribing information in understanding the meaning of "administering." The term must be construed in view of how a POSA would have understand it ***at the time of the filing of the '209 patent***. *Phillips*, 415 F.3d at 1313 (noting that claim construction focuses on "the meaning that the term would have to a person of ordinary skill in the art in question . . . as of the effective filing date of the patent application."). No version of the Alimta® label, let alone the current one, was available when the original application that led to the '209 patent was filed in 2000.

Second, the prescribing information was not prepared by a POSA—*i.e.*, a doctor with experience in oncology or nutritional sciences. Lilly has provided no evidence to indicate who prepared the most recent version of the product labeling, which is typically prepared by regulatory employees.[7] The Federal Circuit has specifically warned against relying upon extrinsic evidence like this. *Phillips*, 415 F.3d at 1318 ("[E]xtrinsic publications may not be written by or for skilled artisans and therefore may not reflect the understanding of a skilled artisan in the field of the patent.").

Third, even if the prescribing information uses "administer" to include "prescribe," as

[7] The original instruction to physicians regarding the use of dexamethasone did not include the phrase "administer dexamethasone." TX 2037 (05/2012 Labeling) at 2; Tr. 170-71. After Lilly became aware of Defendants' argument that "administering" referred to physically putting an agent into the patient's body (Ex. E (Teva's October 2012 Interrogatory Responses) at 5), Lilly replaced the dexamethasone instruction with "administer dexamethasone" (TX 1379 (11/2012 Labeling) at 2).

with dexamethasone,[8] there is no evidence that "administer" is also used to mean "instruct." The prescribing information tells physicians to "[i]nstruct patients to initiate folic acid …" TX 3018 at 2. If Lilly were correct that "administering" encompasses instructing, then the prescribing information instead would tell physicians to "administer" folic acid.

Finally, the fact that an instruction is included in the "Dosage and Administration" section does not mean that an instruction to the patient to take folic acid is an "administration" by the doctor. Every product label has a "Dosage and Administration" section. FDA's guidance states that this "section should include any specific *administration instructions* that are important to the safe and effective use of the drug." Ex. F (FDA Guidance) at 5 (emphasis added). Contrary to Lilly's argument, these instructions concerning administration are not limited to the conduct of doctors. For example, the FDA Guidance includes instructing patients "for sustained release tablets, … do not chew tablets." *Id*. Such an instruction is directed to the patient, not the doctor. Moreover, the FDA guidance uses the term "administering" consistent with Defendants' construction to refer to the dose, route, and timing that agents are put into the patient's body. *Id.* at 4, 6. And contrary to Lilly's arguments, patients as well as doctors are specifically directed to the prescribing information. Tr. 152-53; TX 3017 at 3.

d. Lilly's Other Extrinsic Evidence Is Unrelated To The Present Dispute And Irrelevant

Lilly cites other pieces of "extrinsic evidence" as allegedly supporting its construction. This evidence is unrelated to the present dispute and irrelevant. Lilly cites the expert testimony of Dr. Green. Lilly Br. at 8. But the cited deposition testimony had nothing to do with the

[8] Lilly argues that Dr. Schulz testified that he "administers" dexamethasone by "prescribing" it. Lilly Br. at 7. But that takes Dr. Schulz's testimony out of context. Dr. Schulz was merely acknowledging that the Alimta® prescribing information uses the word "administer," and that he follows that instruction by prescribing dexamethasone. That is not to say, however, that Dr. Schulz agrees that is a proper use of the term "administering" nor that he agrees "administering" means prescribing *or instructing* in the context of the '209 patent claims.

meaning of "administering." Dr. Green was never tasked with construing the term "administering," he never defined the term during his deposition, and there was no follow-up discussion between counsel and Dr. Green regarding the reasoning behind Dr. Green's use of the term "administering." Dr. Green's deposition response using the word is not a construction. It was at most conclusory, and it should therefore be given little weight. *Phillips*, 415 F.3d at 1318; *see also Impulse Tech. Ltd. v. Microsoft Corp.*, Case No. 11-586, 2015 WL 1737663, at *8-9 (D. Del. Apr. 9, 2015) (giving "little weight" to deposition testimony relating to an expert's *invalidity* opinions where the "testimony consisted of a short series of answers given in a deposition, without any follow-up discussion regarding the bases or reasoning behind the answers").

Lilly also refers to briefing from an unrelated litigation regarding the pemetrexed compound patent. Lilly Br. at 8-9. The use of the term "administering" here is just as conclusory as Dr. Green's testimony, and is even further removed from the present dispute. The statements were not made in the context of the '209 patent or how a POSA would understand its claims, and are irrelevant to the claim construction analysis.

2. Lilly's Construction Is Not Supported By The Intrinsic Evidence

After its extensive discussion of extrinsic evidence, Lilly argues that the intrinsic evidence also supports its construction. But Lilly is wrong that its construction finds support anywhere in the intrinsic record. Lilly Br. at 9-12. According to Lilly, the '209 patent claims are directed to the treatment of cancer, and because physicians treat cancer patients, every step of the claim must be directed to a physician. *Id.* at 10. Lilly's argument is classic circular reasoning—because a doctor treats cancer, all the claim terms must be construed to include the conduct of the doctor. While Lilly could have drafted the claims to focus on the conduct of the doctor, the claims as issued are not so directed. Rather the claims are directed to "administering" folic acid,

vitamin B12, and pemetrexed, and they contain steps that relate to how those agents get into the body. Nothing limits the claims to only what a doctor does.

There is no support in the '209 patent for Lilly's attempt to limit the construction of "administering" to conduct of doctors only. The words of Lilly's construction, "prescribing" and "instructing," appear nowhere in the '209 patent specification. Lilly relies upon a single passage from the '209 patent specification, a clinical trial example, that uses the word "administering." In particular, Lilly argues that because under the section header "method of administration," the patent refers to "suppl[ying]" oral folic acid pills to patients for them to take, administering must include instructing. Lilly Br. at 11 (citing TX 1 at 9:5-17). But nothing in the patent indicates that it is the doctor who "administers" folic acid in this clinical trial. To the contrary, the patent indicates that the patient "take[s]" the folic acid. *Id.* at 9:14, 26. And the description of folic acid can be contrasted with vitamin B12, where the patent describes this clinical trial as "obtain[ing] *and administer[ing]* [an] intramuscular injection." *Id.* at 9:19-20 (emphasis added). The description of this clinical trial does not support Lilly's broad construction.[9]

Finally, Lilly has not demonstrated that the prosecution history supports narrowing the meaning of "administering" to include only actions performed by physicians. Lilly Br. at 11-12. Lilly argues that during prosecution it relied upon the language in the physician prescribing information that physicians instruct patients to take folic acid, and thus the term "administering"

[9] In a footnote, Lilly also relies on other evidence from the specification. Lilly Br. at 11, n.3. First, Lilly states that the patent refers to "administering" folic acid in mice studies, and because mice cannot "administer" folic acid to themselves, Defendants' construction is wrong. During the earlier claim construction briefing, Lilly argued that such mice studies are irrelevant because the claims are directed to administering agents to human patients. *See, e.g.*, D.I. 94 at 27-29. Regardless, in the mice study, there is no dispute that the scientist conducting the study physically provides the folic acid. And even Lilly does not argue that the scientists prescribe, instruct, or direct the mice to consume the folic acid. The cited passage therefore does not support Lilly's proposed construction.

Second, Lilly argues that the specification equates "treatment" and "administering." Even if the two terms meant the same thing, which Lilly simply asserts in a footnote, it does not change the fact that given the text of the '209 patent claims and specification, "administering" must refer to putting agents into the body.

must cover that instruction. *Id.* The Federal Circuit has explained that the prosecution history cannot be used to narrow claim terms absent a clear disavowal or contrary definition. *Digital-Vending Servs. Int'l, LLC v. Univ. of Phoenix, Inc.*, 672 F.3d 1270, 1276 (Fed. Cir. 2012). The prosecution history contains no such disclaimer of claim scope. During prosecution, there was no discussion of who (a patient or a doctor) "administered" folic acid as claimed. TX 201 at 454-55. Rather, Lilly simply argued to the PTO that if a patient put folic acid into her body, after following the physician's instruction to do so according to the prescribing information, toxicity was reduced. *Id*. There was no discussion about ***who*** administered the folic acid, and no clear disclaimer that the administration steps had to be performed by a physician. *Id*. Here, the prosecution history does not support Lilly's attempt to limit "administering" to only the actions of the doctor.

C. Courts Have Construed Administering Consistent With Defendants' Construction

Other courts have construed the term "administering" as Defendants propose in similar contexts. How one court construes the term may inform another when the underlying intrinsic evidence, and dispute, is similar. Indeed, there are many cases in which a court adopted a construction of "administering" similar to that proposed by Defendants here, over a construction similar to Lilly's, based on similar intrinsic evidence. *See, e.g.*, *Abbott Biotech. Ltd. v. Centocor Ortho Biotech, Inc.*, No. 09-40089, 2011 U.S. Dist. LEXIS 90176, at *19 (D. Mass. Aug. 12, 2011) ("The act of prescribing is clearly distinct from the subsequent act of administering medication."); *Medical Research Inst. v. Bio-Engineered Supplements & Nutrition, Inc.*, No. 05-417, 2007 U.S. Dist. LEXIS 3576, at *23 (E.D. Tex. Jan. 12, 2007); *Schering Corp. v. Mylan*

Pharms., Inc., No. 09-6383, 2011 U.S. Dist. LEXIS 63825, at *24 (D.N.J. June 15, 2011).[10] And while Lilly attempts to argue that, for some unexplained reason, the context of cancer treatment is different, Judge Andrews in the District of Delaware recently held that "[a]dministering as understood by a person of ordinary skill in the art must be limited to delivering a drug into or onto a mammal" where, as is the case here, "examples of administration" in the patent "describe delivering the drug into or onto the body" in the context of treating cancer. *Andrulis Pharms. Corp. v. Celgene Corp.*, No. 13-644, 2015 WL 3978578, at *3 (D. Del. June 26, 2015).

IV. There Is No Direct Or Indirect Infringement Of The Asserted Claims

No matter what claim construction the Court adopts, doctors do not directly infringe, and the Defendants do not indirectly infringe, the asserted claims of the '209 patent.[11] As the Federal Circuit recently reaffirmed, direct infringement of a method claim requires the patent owner to prove that a single party performs every step of a claimed method. *Akamai*, 786 F.3d at 904. The only exception to this rule allows the combination of conduct of multiple individuals "*only* if one party exercises 'control or direction' over the entire process such that every step is attributable to the controlling party, *i.e.*, the 'mastermind.'" *Muniauction, Inc. v. Thomson Corp.*, 532 F.3d 1318, 1329 (Fed. Cir. 2009) (emphasis added). In other words, the "mastermind" must be able to "obligate" the other party to act. *Akamai*, 786 F.3d at 915. The Federal Circuit has held that unless a party can show agency, a contractual relationship or a joint enterprise, there is

[10] The cases Lilly cites in support of its construction are distinguishable. In *Pozen Inc. v. Par Pharm. Inc.*, "it appear[ed] that Defendants [were] asking the Court to construe 'administering' as it appears in non-asserted method claims only." 719 F. Supp. 2d 718, 724 (E.D. Tex. 2010). Such is not the case here, where method claims are asserted against Defendants, including those that use "administering" to refer to putting agents into the body. Moreover, while the court in *Shire LLC v. Amneal Pharms., LLC* declined to adopt a construction of "administering" consistent with Defendants' in the present case, it did not adopt a construction like Lilly's either, and it suggested that putting the recited drug into the patient's body was a necessary element of the method claims. No. 11-3781, 2013 U.S. Dist. LEXIS 111773, at *54-55 (D.N.J. Aug. 8, 2013). Finally, unlike the method claims in the present case, the methods claims at issue in *Janssen Prods., L.P. v. Lupin Ltd.*, did not use the term "administering" to describe how, when, or at what dose, the recited medicinal agents went into the patient's body. No. 10-cv-05954, 2013 U.S. Dist. LEXIS 189016, at * 22-23 (D.N.J. Jan. 7, 2014); Ex. G (U.S. Patent No. 7,470,506).

[11] Because neither Teva nor APP directly treats any patient, Lilly has not asserted, and cannot assert, that any of the asserted claims are directly infringed by Defendants. Tr. 139, 141.

no liability. *Akamai*, 786 F.3d at 904. "[M]ere 'arms-length cooperation' will not give rise to direct infringement by any party." *Muniauction*, 532 F.3d at 1329. Lilly asks the Court to ignore this binding Federal Circuit law to find infringement.

It is undisputed that physicians (or affiliated staff) administer pemetrexed (intravenously) and vitamin B12 (by injection). The issue for the Court to decide is whether the physician alone administers folic acid. To support its argument that the doctor "administers" folic acid, Lilly seeks a broad construction (discussed above) to encompass some conduct by the doctor. Even under this expansive construction of "administer," Lilly cannot escape the reality that it is the patient, not the physician, who physically puts the folic acid into her body (*i.e.*, administers it orally). Tr. 141, 146-47. Consequently, under either parties proposed construction, Lilly's "asserted claims were drafted so as to require the activities of [two actors]," and therefore, it has "put itself in a position of having to show that the allegedly infringing activities of [patients] were attributable to [physicians.]" *Akamai*, 786 F.3d at 915. Lilly cannot meet this burden.

A. No Single Actor Will Administer Pemetrexed, Vitamin B12 And Folic Acid

There can be no direct infringement because Lilly did not prove that any physician, following Defendants' proposed labeling, actually performs, or "controls or directs" the performance of, each and every step of the asserted '209 patent claims.

1. The Physician Does Not Literally Perform The Claimed Step Of Administering Folic Acid

All of the asserted claims of the '209 patent require the step of administering folic acid. The physician will not perform this claimed step. Under the proper construction of this term, Lilly does not even contend that the physician (or affiliated staff) literally puts the folic acid into the patient's body. Lilly does not contest that the patient will purchase the folic acid in the form of a multivitamin or over the counter pill, and administer it to herself, as directed by the product

insert and patient information. Tr. 150, 217-18; TX 3017; TX 3018. Thus, under Defendants' proposed construction of "administering" there is no question that a second actor—the patient—performs the step of administering folic acid.

No single actor "administers" folic acid, vitamin B12 and pemetrexed even under Lilly's (incorrect) proposed construction. Assuming, *arguendo*, that Lilly's proposed construction is correct, Dr. Chabner admitted at trial on multiple occasions that the act of "administration" is not complete until folic acid is put into the body. Tr. 14647 ("Q. The drug has to get into the patient's body for the completion of the administration process, right? A. That's correct"), 141 ("Q. But the administration is not completed until the drug actually gets into the patient's body, right? A. That's correct."). Thus, even under Lilly's proposed construction, while the doctor participates in the administration, it is not completed until the ***patient*** puts the folic acid into her body. In this scenario, the combined actions of two actors are required to complete the claimed administration of folic acid (*i.e.*, a physician to "prescribe, instruct, direct and cause it to be carried out" and a patient to actually carry out the step of administration). Under any proposed construction, no single actor performs each and every step of the '209 patent claims.

Lilly's attempt to distinguish the need for the patient to complete the administration of folic acid fails. Lilly cites *Ultratec, Inc. v. Sorenson Commc'ns, Inc.*, 45 F. Supp. 3d 881 (W.D. Wis. 2014) and *SiRF Tech., Inc. v. Int'l Trade Comm'n*, 601 F.3d 1319, 1331 (Fed. Cir. 2010) for the proposition that the physician need not have control over the complete step of administering folic acid, because the act of putting folic acid into the body is "unclaimed." But, for the claims at issue here, Lilly is wrong. In *Ultratec* and *SiRF* the claims at issue only required the actions of one party; the alleged conduct of a second actor was not specifically required by the claims. Here, there is no dispute that the claims require that folic acid be

administered, and Lilly (and Dr. Chabner) have acknowledged that "administering" requires getting the folic acid into the patient's body. Tr. 138, 141, 146-47, 153-54. The conduct of the second person is not "unclaimed" but rather falls within the claim term "administered."

2. The Physician Does Not Otherwise Have Control Or Direction Over Administering Folic Acid

a. There Is No Agency Relationship, Contractual Relationship Or Joint Enterprise Between the Physician And Patient

The actions of the physician and the patient cannot be combined to find direct infringement. Lilly contends that even if the Court determines that the patient is required to complete the step of administering folic acid, the physician still literally infringes the '209 patent claims by "exercising control or direction over the administration of folic acid." Lilly's Br. at 22. However, the legal test for "control or direction" requires more than evidence that suggests the physician and patient may jointly work together to treat the patient's cancer. The Federal Circuit has explained that the standard for combining the actions of multiple people is high. Under the controlling *Akamai* decision, control or direction can only be shown in situations where the direct infringer can be held vicariously liable for the acts committed by another. 786 F.3d at 904. The Federal Circuit has provided only three situations where this may occur: principal-agent relationship, a contractual relationship, or in circumstances in which parties work together in a joint enterprise functioning as a form of mutual agency. None apply here.

Lilly makes no attempt to demonstrate that any of these legal relationships exist between the doctor and the patient. Lilly's post-trial brief does not even argue that in the context of the physician and patient performing the claimed steps of the '209 patent that a principal-agent relationship exists, that a contractual relationship exists, or that a joint enterprise has been formed. Instead, Lilly argues that the doctor "controls" a patient in the same way the doctor "controls" a nurse. But this highlights the flaw in Lilly's reasoning. Lilly argues that the doctor

> place[s] a specific order for each of the agents the patient is to receive, which they expect others to execute. And those others – *whether a nurse or a patient* – execute those orders on behalf of the physician, by infusing, injecting, or ingesting the agent as directed.

Lilly Br. at 24 (emphasis added). Lilly's suggestion that the relationship between the doctor and nurse, and the doctor and the patient are legally the same is wrong. Doctors do not "expect" a nurse to carry out their orders; rather, the nurse is ***hired to do just that***. When the Federal Circuit refers to "control or direction," the court is discussing this type of legal relationship.

But the relationship between a doctor and a patient is ***not*** the same. The Federal Circuit in *McKesson Techs., Inc. v. Epic Sys. Corp.*, found the doctor-patient relationship lacked the required "control or direction" for a finding of vicarious liability. No. 10-1291, 2011 U.S. App. LEXIS 7531, at *10, 26-27 (Fed. Cir. Apr. 12, 2011), *vacated on other grounds, Akamai Techs., Inc. v. Limelight Networks, Inc.*, 692 F.3d 1301, 1305-06 (Fed. Cir. 2012) (en banc). The plaintiff in *McKesson* argued that physicians controlled the acts of patients generally because of the "special nature" of the doctor-patient relationship, including because "[t]he phrase 'doctor's orders' says it all" and "the existence of a doctor-patient privilege," *Id*. at *10. But the Federal Circuit rejected that argument: "a doctor-patient relationship does not by itself give rise to an agency relationship or impose on patients a contractual obligation such that the voluntary actions of patients can be said to represent the vicarious actions of their doctors." *Id*. Instead, the court found that patients will "act[] principally for their own benefit and under their own control." *Id*. at *11; *see also* Lilly Amicus Brief, 2014 WL 1319146, at *10.[12] Lilly's argument, that the patient follows the doctor's orders, is the same as that rejected by the Federal Circuit. The Court

[12] Lilly simply dismisses this case as irrelevant because it is "in the context of claims to the use of a computer system." Lilly's Br. at 25, n.9. While it is true that the technology at issue in *McKesson* related to the use of computer software by patients and physicians, Lilly ignores that the Federal Circuit's discussion of the physician-patient relationship was not so limited (as Lilly itself acknowledged to the Supreme Court).

must similarly reject the argument.

The arms-length nature of this relationship is evidenced by the very facts that Lilly claims are irrelevant. Lilly's Br. at 24 n.8. If physicians truly controlled the acts of the patient, such that the patient was legally obligated to act based on that relationship, the physician would have complete control over whether the patient takes a multivitamin or other form of over-the-counter folic acid; whether the patient takes 350 µg or 1000 µg or some other dose; when and how often the patient takes folic acid; and where the patient gets it from. It was Lilly that drafted and obtained method claims that require two actors to complete, and under the law of the Federal Circuit those two actors do not have a sufficient relationship to find any single party (*i.e.*, the physician) directly infringes the patent. *Akamai*, 786 F.3d at 909 ("It would thus be unwise to overrule decades of precedent in an attempt to enforce poorly-drafted patents.").

Lilly's but-for argument (*i.e.*, physicians will not administer pemetrexed unless patients administer folic acid) is legally insufficient. In many of the cases previously decided by the Federal Circuit, without one party's actions all of the claimed steps will not be performed. As illustrated by *Akamai*, providing "instructions" on how to perform a claimed step (and requiring performance of that step before subsequent steps will be performed) is legally insufficient, because the end-user is still free to decide what action, if any, they will perform. *See Akamai*, 786 F.3d at 915 ("Limelight's customers decide what content, if any, they choose to have delivered by Limelight's [content delivery network] and only then perform the 'tagging' and 'serving' steps. The form contract does not *obligate* Limelight's customers to perform any of the method steps.") (emphasis in original).

Finally, Lilly cites Dr. Chabner's testimony concerning actions a doctor ***may*** take to encourage the patient to follow the doctor's directions. Lilly Br. at 24. But the speculative

conduct identified by Dr. Chabner at trial is legally insufficient to establish control or direction because none of those actions *require* the patient to act. The doctor takes these actions precisely because she cannot make the patient act, demonstrating (as a legal matter) that the doctor does not have sufficient control or direction over the patient's actions. At most, the doctor tries to implement a treatment plan by instructing the patient to take folic acid. The Federal Circuit has held, however, that "control[ling] access to [a] system and instruct[ing] [others] on its use is not sufficient" to demonstrate "control or direction." *Voter Verified, Inc. v. Premier Election Solutions, Inc.*, 698 F.3d 1374, 1384 (Fed. Cir. 2012) (quoting *Muniauction*, 532 F.3d at 1330). Thus, "[g]iving instructions or prompts to the third party in its performance of the steps necessary to complete infringement, or facilitating or arranging for the third-party's involvement in the alleged infringement, are not sufficient." *Emtel, Inc. v. Lipidlabs,* Inc., 583 F. Supp. 2d 811, 834-35 (S.D. Tex. 2008).

b. The Principles of Copyright Law And State Tort Law Have No Bearing On Direct Infringement

Rather than addressing the Federal Circuit cases concerning direction and control, Lilly instead discusses copyright and various state court cases allegedly concerning "vicarious liability." But these cases are inapposite and Lilly cannot establish that the physician has control or direction over the actions of the patient. *See Akamai,* 786 F.3d at 905-06, 911-14 (refusing to apply common law theories of joint liability).

Lilly cites two copyright infringement cases that do not apply to the "direct" infringement of a patent claim. Lilly Br. at 23; *see Metro-Goldwyn-Mayer Studios lnc. v. Grokster, Ltd.,* 545 U.S. 913 (2005); *Sony Corp. of Am. v. Universal City Studios, lnc.,* 464 U.S. 417 (1984). As *Sony* recognizes, copyright law is different from patent law in that it does not have a statutory basis for infringement by multiple people. 464 U.S. at 435. Patent law, on the other hand,

statutorily provides combined liability under sections 271(b) and (c), and requires an individual perform each and every element of a patent claim to directly infringe under section 271(a). The Federal Circuit's binding precedent requires a single actor for direct infringement of method claims, and plainly distinguishes the copyright cases cited by Lilly.

Lilly's citation to various state law tort cases is similarly unavailing. Lilly's search for limited exceptions to the general rule that a doctor is *not* liable for conduct of a patient merely establishes the general rule that the doctor/patient relationship is not one in which vicarious liability applies. For example, *Taylor v. Smith* held the doctor liable when its negligent actions combined with the negligent actions of the patient caused injury jointly (*i.e.*, joint tortfeasor liability). 892 So.2d 887, 896-97 (Ala. 2004). The Federal Circuit has made plain that joint liability is *not* sufficient to demonstrate direction and control. *Akamai*, 786 F.3d at 905 ("We begin by considering whether § 271(a) incorporates joint tortfeasor liability . . . [u]nquestionably, it does not."). The state tort law cases cited by Lilly found liability because of reasonably foreseeable conduct, not because the patient was acting within the scope of his or her relationship with the doctor or that the doctor was vicariously liable. The string cite of cases do not establish that the conduct of the patient can be attributed to the doctor for patent infringement.

3. The Doctrine Of Equivalents Theory Is Factually And Legally Flawed

Lilly's final direct infringement argument is that even if the doctor does not literally "administer" the folic acid, the doctor's instructions to the patient are equivalent to administering folic acid. This argument is both legally and factually flawed. As a legal matter, Lilly's argument would swallow the divided infringement rule adopted by the Supreme Court and Federal Circuit. The myriad cases explaining and applying the direction and control test would be unnecessary if a mere instruction were "equivalent" to carrying out the conduct. Moreover, the equivalence argument still relies on the conduct of two legally distinct individuals—the

doctor instructs, and the patient administers. As a factual matter, merely instructing the patient to take folic acid is not substantially the same as actually administering it. The doctor lacks control over certain details and cannot ensure that the folic is actually taken. There is still no direct infringement.

a. Lilly's Theory Fails As A Matter of Law

Lilly's doctrine of equivalents argument—that a physician instructing a patient to take folic acid, and then the patient administering it orally, is legally equivalent to the physician actually administering the folic acid to the patient—would vitiate the law on divided infringement. *Cf. Akamai*, 786 F.3d at 905, 907-09 (rejecting joint action theory of liability because it would render other statutory provisions redundant). Lilly does not deny that the prior Federal Circuit cases on divided infringement would have come out differently under its theory. Instead, Lilly's response is that the issue of doctrine of equivalents was not raised in those cases. Lilly's Br. at 21 n.7. Whether this theory was raised, however, does not change its broad implications; it would circumvent the law requiring a single actor perform every step of a method claim. According to Lilly, a physician instructing a patient to take folic acid, and then the patient following that instruction, is legally equivalent to the physician actually administering the folic acid to the patient. In other words, the combined acts of two individuals (the patients' administration of folic acid and the physicians' instruction to do so) are equivalent to the act of physicians' actually administering folic acid. If the law of divided infringement were so easily avoided, then the Federal Circuit and Supreme Court need not have spent more than five years wrestling with these questions. No court has ever found infringement by equivalents on such a theory, nor should it be found here. To the contrary, the Federal Circuit has held that "[e]ncouraging or instructing others to perform an act *is not the same as performing the act oneself* and does not result in direct infringement." *Akamai*, 786 F.3d at 904 (emphasis added).

This control and direction standard is a very strict standard. The Federal Circuit has explained that absent a "*principal-agent relationship*" or "*contractual arrangement*", it has declined to find the "actions of one party can be legally imputed to another, such that a single entity can be said to have performed each and every element of the claim." *Akamai*, 786 F.3d at 904, 909 (emphasis added). Under Lilly's doctrine of equivalents theory, "instructions" that fall far short of this standard would result in infringement under the doctrine of equivalents. The Court should reject Lilly's doctrine of equivalents argument because it is an exception that swallows the rule.

Lilly's doctrine of equivalents argument is also legally flawed because it reads out the limitation "administer" and replaces it with the different concept of "instructing." The Supreme Court has expressly counseled against any application of the doctrine of equivalents that allows for "such broad play as to effectively eliminate [a claim] element in its entirety." *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 29 (1997). Lilly cannot obtain through the doctrine of equivalents claim scope it explicitly failed to get through claim construction.[13]

b. Lilly's Theory Fails Because It Still Requires Two Actors To Perform All The Steps Of The Asserted Claims

Lilly's doctrine of equivalents theory is further flawed because it still requires the conduct of two actors to carry out the claimed steps. While Lilly argues that the argument is directed only to the conduct of the doctor, Lilly Br. at 19-20, that is incorrect. Focusing only on the conduct of the doctor, no folic acid would get into the patient's body. Rather, to argue that the function, way and result are equivalent, Lilly relies upon the conduct of both the doctor (in instructing) ***and the patient*** (who actually takes the folic acid pill or multivitamin). There is no

[13] Additionally, if Lilly is correct that the '209 patent discloses the act of instructing patients to take folic acid (Lilly Br. at 11), then by expressly disclosing this subject matter without literally claiming it, Lilly cannot recapture it under the doctrine of equivalents. *Johnson & Johnston Assocs. Inc. v. R.E. Serv. Co., Inc.*, 285 F.3d 1046, 1054 (Fed. Cir. 2002).

dispute that the conduct of the doctor alone is ***not*** equivalent. Lilly's doctrine of equivalents theory suffers the same problem as its literal infringement theory—direct infringement of the asserted '209 patent claims requires more than one actor (*i.e.*, a doctor and a patient).

c. Lilly's Theory Fails Because Mere "Instructions" Are Not Equivalent To The Physical Act Of Administering Folic Acid

Lilly's doctrine of equivalents argument is also flawed as a matter of fact. A physician "instructing" a patient to take folic acid in combination with the additional step of the patient putting folic acid in his or her own body is not equivalent to the physician actually administering folic acid. The physician that physically puts the folic acid into the body will have complete control over the form of folic acid administered, the route of administration, the dose administered and the frequency of administration. Tr. 224. In contrast, the physician who merely provides an instruction and relies on the actions of the patient will not know whether, when or how much of the drug will actually be put into the body. *Id.* Even Dr. Chabner conceded that in his view these can only be equivalent "so long as the patient swallows both pills." Tr. 133. But that is precisely the point; the physician who merely "instructs" a patient to take folic acid does not know if the patient will swallow the pill. Tr. 217-18, 219. Because the control of the doctor is substantially different when she actually administers a drug compared to when she merely instructs a patient to take it, Lilly's theory fails as a matter of fact.

B. Defendants Will Not Induce Infringement Or Contribute To The Infringement Of Any Of The Asserted Claims

Lilly has failed to prove infringement for an additional reason. As discussed in Defendants' pre-trial brief (D.I. 361 at 7-9), to succeed on a claim of induced infringement, the patentee must show "that the alleged infringer knowingly induced infringement and possessed *specific intent* to encourage another's infringement." *MEMC Elec. Materials, Inc. v. Mitsubishi Materials Silicon Corp.*, 420 F.3d 1369, 1378 (Fed. Cir. 2005) (citation omitted) (emphasis

added). The intent requirement for inducement requires the inducer to "have an affirmative intent to cause direct infringement." *DSU Med. Corp. v. JMS Co*., 471 F.3d 1293, 1306 (Fed. Cir. 2006) (en banc). Thus, Lilly was required to prove that Defendants will knowingly induce, with specific intent to encourage, physicians to perform every step of the claimed methods.

The Federal Circuit, in *Takeda Pharms. USA, Inc. v. West-Ward Pharm. Corp., et al*, provided clear guidance on this issue for the Court. 785 F.3d 625, 631 (Fed. Cir. 2015). The *Takeda* court explained that "[t]he mere existence of direct infringement by physicians, while necessary to find liability for induced infringement, is not sufficient for inducement." *Id*. at 631. The court further explained that "mere knowledge of possible infringement by others does not amount to inducement; specific intent and action to induce infringement must be proven." *Id*. In the context of Hatch-Waxman patent litigation, "vague label language cannot be combined with *speculation* about how physicians *may act* to find inducement," because the court found "[t]his would seem to too easily transform that which . . . is legally irrelevant,—mere knowledge of infringing uses—into induced infringement." *Id*. at 632 (internal citation and quotation marks omitted). The Federal Circuit refused to rely on such speculation, holding that "[s]peculation or even proof that some, or even many, doctors would prescribe [a drug] for [an infringing treatment] is hardly evidence of inevitability." *Id*. at 633. Last, the plaintiffs in *Takeda* improperly asked the court "to look outside the label to understand the alleged implicit encouragement in the label." *Id*. at 634.

Here, as in *Takeda*, Lilly's ***speculation*** as to how some doctors ***may act*** is insufficient to find Defendants have a specific intent to encourage another's infringement. Lilly Br. at 24. There is absolutely no evidence that the Defendants have knowledge that some doctors may use "stern" language when counseling patients, that some doctors may withhold treatment, that some

doctors may require patients to sign some sort of consent form that, according to Lilly, obligates them to administer folic acid, or that some doctors may instruct patients to keep pill counts and pill diaries. Tr. 151 ("Q. What you tell them goes beyond what the instruction is in this patient information that's provided [] right? A. That's true."), 223-24.

All that Defendants have knowledge of is the prescribing information (TX 3018) and patient information (TX 3017). Those documents clearly and emphatically state that the patient is to administer the folic acid and the doctor is to administer the vitamin B12 and pemetrexed. Thus, the only knowledge regarding the specific intent of the Defendants adduced at trial, is that Defendants prescribing and patient information instructs physicians to administer vitamin B12 and pemetrexed and instructs patients to administer folic acid to themselves. Defendants' do not instruct physicians to administer folic acid. Based on the clear statements in Defendants' prescribing and patient information and the Federal Circuit's admonishment of relying on speculation of how some doctors may act, there is insufficient evidence to hold Defendants liable for induced infringement.

Nor would Defendants be liable for contributory infringement. The use of Defendants' ANDA products in accordance with their proposed labeling is a substantial noninfringing use because no single actor would perform each and every step of the '209 patent claims. *See Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1327 (Fed. Cir. 2009). Moreover, as discussed with respect to induced infringement, there is no evidence that Defendants have knowledge that their ANDA products will be used in an infringing manner. *See* 35 U.S.C. § 271(c).

V. Conclusion

For the above reasons, the Court should find that there is no direct or indirect infringement of any of the '209 patent claims.

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CERTIFICATE OF SERVICE

I certify that on July 10, 2015, a copy of the foregoing document was filed electronically. Notice of this filing will be sent to the following parties by operation of the Court's electronic filing system.

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